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EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,088 10/612,088	SANGER, WALLACE D.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,9,17 and 20* is/are pending in the application.

4a) Of the above claim(s) *2-7,10-16,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,8,9,17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.

DETAILED ACTION

1. Claims 1, 5, 8-9, 17 and 20 are pending. Claims 2-4, 6-7, 10-16 and 18-19 are withdrawn.

Election/Restrictions

2. This application contains claims 2-4, 6-7, 10-16 and 18-19 drawn to inventions nonelected in the reply with traverse filed on October 15, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1, 5, 8-9, 17 and 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained and made final. Applicants' arguments have been fully considered but are not deemed persuasive.

Applicants argue that their patent specification meets the written description requirement because it provides sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention with all of its limitations using such descriptive means as structures, figures, diagrams and formulas that fully set forth the claimed invention, which can include express, implicit or inherent disclosure.

Applicants first contend that the Malliard reaction is a well known reaction to persons having ordinary skill in the art and that the operating conditions necessary for the Maillard reaction to occur are also well known to persons having ordinary skill in the art. The examiner respectfully

disagrees. The examiner provided a detailed explanation and reference, which set forth that although the general concept of the Malliard reaction is known, the operating conditions are not. Applicants have not provided any documentation to show otherwise. As previously set forth by the examiner The Specification discloses a Peptide Model Reaction, similar to a Maillard Reaction, with a specific sugar, reactant, and pH range along with Sensory Profiling. Specification, pp. 11-12. While the specification provides limited guidance with respect to the Maillard reaction, the mechanism of the Maillard reaction is very complicated and strongly affected by factors, which influence the different chemical reactions involved, i.e. temperature and duration of heating, pH and presence of weak acids and bases, water content, type of reactant, amino acid and sugar ratio and oxygen content. See Davies, et al. The Maillard Reaction application to Confectionery Products, Confectionary Science, 1997, pp. 1-33, http://courses.che.umn.edu/00scn8334_lf/FSCN8334_Reading.html, last updated September 26, 2000, particularly pp. 3 and 13. While the Specification provides limited parameters, i.e. one of the claimed sugars, some information on heating but not all, the length of time the pre-heating occurs, the water content, amount of propylene glycol, how long the mixture was heated – length of time is important and we know it was heated up to 60 minutes but it could have been anywhere from 1-60. Additionally, the rate of reaction depends on the rate at which the sugar ring opens to the reducible, open-chained form and this increases with increasing pH, i.e. pentoses react more rapidly than hexoses and relative rate of browning also depends on the extent to which the reaction mixture is buffered, i.e. in unbuffered media, the rate of browning of fructose with amino acids is greater than that of glucoses and for hexoses the order of reactivity is D-galactose>D-mannose>D-glucose and reducing disaccharides are considerably less reactive

than their corresponding monomers. *Id.* at 13-14. Moreover the Maillard reaction, also is dependent upon the type of amines, i.e. basic amino acids are more reactive than neutral or acidic amino acids, which led one author to suggest a classification of amino acids into three groups depending on the extent of browning when reacted with glucose at different, pH, and 121 degrees C for 10 minutes, while other results show that comparisons can only be used if the same pH and buffering conditions exist, i.e. the effect of pH is especially significant due to the different pK_a values of the amino acids. *Id.* at 15. Thus, it has been determined that at least the amount of browning is not, *per se*, proportional to the conversion of amino acid or peptides, as the degree of browning depends on the type of melanoidin formed during the Maillard reaction and that small peptides are more reactive than corresponding peptides. *Id.* at 15-16. The Specification fails to provide any guidance with respect to the differences between the peptides and their different rate of reaction for the various sugars, i.e. only one sugar, fructose, is disclosed, or the different types of amines that need to be taken into account because of the different types of amino acids in the di-peptides. Additionally, the Specification lacks guidance on the reactant ratio, i.e. the extent of browning seems to vary according to the sugar/amine ratio, but the extent that this will occur is unknown. *Id.* at 16-17. Further, different flavors are formed at different temperatures, thus the length of heating is also important as the formation melanoidins usual occurs at a rate which increases in proportion to the square of the reaction time at any given temperature and different flavors are formed depending on the extent of the reaction, however, most temperature studies have only considered color development and, thus, there is only a little information on the effect of temperature on the effect on flavor formed during browning, very little data exists on rate or activation energies, thus, at any given

temperature-time combination, a unique aroma profile is produced. *Id.* at 19-21. The specification lacks guidance as to the temperature-time combination, and only states minimally that the predefine mixture was added to preheated propylene glycol and does not specify any length of time and that the reaction mixture was heated up to 60 minutes, which could be anywhere from 1 up to 60 minute and does not specify any temperature for the heating. Specification – Peptide Model Reaction – Pg. 11. Thus, there it is uncertain what if any flavor compound is obtained. Davies discloses that for the first stage of the Maillard reaction to occur, water is essential and thus, the rate of the reaction is dependent on the amount of free water available as related to water activity and that the temperature-moisture profile will control the rate of flavor and color development. Davies, pp. 22-24. However, the specification lacks guidance with respect to the amount of water to be used and only provides limited guidance with respect to the fact that a reactant is used, i.e. propylene glycol. Davies also discloses that the pH has a significant effect on the Maillard reaction and that in general the rate and extent of browning increases with increasing pH, with an optimum above pH 7, leading to a change in the mechanism of the reaction and, hence to the formation of different and volatile and colored products – noting that the pH dependence of the initial step of the reaction can be related to the amount of the unprotonated amine present, the rate of the Maillard reaction is lower at a pH lower than the pKa of the reactive amino group, that one should also note that as temperature increases the pH decreases, and that the rate of the reaction is also dependent on the concentration of acyclic sugar present as noted earlier. The Specification lacks guidance as to the pH with different sugars, although it does utilize the optimum range in the model, it makes

no discussion of whether this range would always be appropriate taking all of the other factors into account.

Applicants arguments that the specification on page one discloses that during roasting of cocoa beans various chemical reactions occur such as Maillard –type reactions and thermal degradation and that the Maillard reaction involving peptides, amino acids and reducing sugar; that they have identified multiple di-peptides during extensive studies that give rise to a savor[1] not expect to occur in or be obtained from cocoa bean generates compounds that are deemed to eventually contribute to the final cocoa/chocolate flavor, i.e. flavor active compounds all derivable from cocoa beans obtained by subjecting one or more di-peptides to a Maillard reaction with reducing sugars. The Applicants specifically argue that the specification provides clear teaching for a person having ordinary skill in the art to immediately understand which compounds would provide which specific flavors because selected peptides are disclosed in the specification that provide chocolate, caramel and meat flavors, as shown by the olfactory test of all of the dipeptides listed in Table 3. Applicants arguments are that example 1 provides detailed reaction conditions such as amounts, temperatures, pH and reaction time of 60 minutes to answer

[1] Noting that savor is not equivalent to flavor. Savor is defined by multiple dictionaries as a smell or taste of something. See, e.g. The Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2004, pg. 1, http://dictionary.cambridge.org/define.asp?key=70004&dict=CALD, printed June 8, 2004; The American Heritage Dictionary of the English Language: Fourth Edition, 2000, pp. 1-2, http://www.bartleby.com/61/74/S107400.html, printed June 8, 2004; Infoplease Dictionary, 2000-2005, pg. 1, http://www.infoplease.com/dictionary/savor, printed June 8, 2004. While flavor/flavour is perceived with the combined senses of taste and smell/a substance used to give food or drink an identifiable or distinctive taste/how food or drink tastes or a particular taste itself – noting an archaic meaning to be an odor or fragrance alone. Encarta World English Dictionary, North American Edition, 2005, pp. 1-2, http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861674021; Dorland's Illustrated Medical Dictionary, W.B. Saunders, 2002, pp 1-16, esp. pg. 9, http://www.merksource.com/pp/us/cns/cns_hl_dholands.jspzQzpgzEzzSzppdocszSzuszSzcommonzSzdorlan..., printed June 8, 2005; Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2004, pp. 1-2, http://dictionary.cambridge.org/define.asp?key=29532&dict=CALD, printed June 8, 2004; Hormel Glossary, 1999-2005, pg. 1, http://www.hormel.com/kitchen/glossary.asp?ProcessPrint=true&Print/Category=glossary&Pr..., printed June 8, 2005. Thus, the difference between savor and flavor is that savor can be either component of taste or aroma and flavor always has the taste component and may have the aroma component.

the examiner's arguments with respect to the concerns raised by Davies. However, the examiner respectfully disagrees. These parameters were specifically discussed in the previous Office Action and reiterated above. Example 1 is the Peptide Model Reaction and as set forth above discloses only a predefined mixture of a dipeptide (no disclosure of what is in the mixture/amounts/ratios/proportions/other components) one sugar (D-fructose) and its amount, the amount of propylene glycol, a pH range (not a pH) adjusted with 0.01N NaOH and contrary to Applicants assertion a range to time for heating, "The reaction mixture was heated up to 60 min, cooled to room temperature and stored at 4 degrees C." Specification, pg. 11, lines 28-30. No where is there any teaching that 60 minutes was the "preferred time" of the reaction as stated in the Applicants response. Moreover, the Maillard reaction is much more complex and Applicants never answered the arguments set forth above about the various temperatures, timing, pHs, sugars, buffers, etc. that would lead to no Maillard reaction, flavorless compounds, no compounds, etc or the unpredictability of the overall reaction one you pass one amino acid. Applicants mere assertion that it is well known does not overcome the teachings of Davies and the unpredictability involved.

Applicants argue that they obtained flavors for all of the di-peptides listed in Table 3. They argue that the words savor, flavor, aroma, body, smell, are used interchangeably in the specification because this is often the case during general use. As was shown by the examiner utilizing a plethora of dictionaries this is just not the case, savor and flavor and aroma all have different meanings in general use. Flavor is distinctive from savor and aroma. In fact, aroma is if anything an archaic use for flavor and thus not a general or accepted use. Moreover, the evaluation of the di-peptides compounds was done according to the specification strictly by

sniffing them, and then on a large scale again by olfactory (smell) evaluation. Specification, pg. 8, lines 3-7 and Table 3 and pg. 12. Not once does the specification ever state that any of the di-peptide compounds were ever tasted or placed into foods/beverages for tasting.

Applicants arguments that a large selection of reducing sugars and solvents are disclosed in the specification at pg.3, lines 20-24 and claims 5 and 9, merely bolsters the arguments set forth in Davies. As previously set forth without specifics, there is no disclosure of how to use them in a Maillard reaction for the reasons previously set forth because it is not readily understood by a person having ordinary skill in the relevant art what under condition sufficient to form the flavor active compound would be.

Applicants claim "a flavor active compound obtained by subjecting one or more peptides selected from the group consisting of ... to a Maillard reaction with reducing sugars under conditions sufficient to form the flavor active compound." However, the Specification lacks adequate written description such that one of ordinary skill in the art would immediately envisage the product claimed from the disclosed process, i.e. any and all compounds/flavors - these would consist of a vast and nuanced set of "flavors/aromas" ranging from bitter to sweet/vegetable to flower to meat to nut/vanilla to chocolate to coffee, etc.. The Specification states the specific peptides are obtainable from cocoa beans and give rise to particular and distinct savor when subject to a Maillard reaction with reducing sugars for the preparation of a chocolate flavor, specifically a cocoa and caramel flavor, a floral or more specifically, a bonbon flavor, bready flavor, or a roasted or meaty flavor. Specification, pg 1, lines 9-13. The Specification further discloses that the size of the peptides and their amino acid contents/sequence play an important role in flavor development and that thermal reaction of a

mixture of fructose/glucose and hydrophobic amino acids under low water activity medium, e.g. glycerol or propylene glycol, etc. give rise to a chocolate-like **aroma**. Specification, pp. 1-2. The Specification adds that using this type of react **flavor** as a base and combining it with certain top notes, most prominent, vanilla, chocolate-like flavor concentrates *could be* produced. Specification, pg. 2. The Specification utilizes flavor and aroma interchangeable and also utilizes the word savor, which can mean the property of a thing which affects the organs of taste or smell and states that the compounds obtained from the Maillard reaction or generically the peptides listed, may be sued for the preparation of any product, wherein an aroma provided by the subjective compounds is desired. Specification, pp. 2-3. The Specification then shows how to identify the di-peptides from cocoa Figs. 1-3 and pp. 4-7. Once again, the Specification speaks of the "flavors" in terms of aroma to determine the potential of the di-peptides. See, pg. 7, line 31 – pg. 10, line 2.

However, nowhere, is there any demonstration of any tasting profile, specific compounds obtained, or any specific tastes that are obtained, or a specific reaction performed on a specific di-peptide to obtain a specific compound that would provide a specific taste not an aroma. Nor are any specific compounds themselves provided from the outcome of the reaction itself. While the specification provides limited guidance with respect to the Maillard reaction, the mechanism of the Maillard reaction is very complicated and strongly affected by factors, which influence the different chemical reactions involved, i.e. temperature and duration of heating, pH and presence of weak acids and bases, water content, type of reactant, amino acid and sugar ratio and oxygen content, which determine whether or not the Maillard reaction will progress and what products will be products, i.e. flavor or not, as set forth in the arguments above citing Davies, et al.

Thus, while the Specification sets forth recitations of "flavors" obtainable by subjecting di-peptides to a Maillard reaction with reducing sugars under conditions sufficient to form the flavor active compound, the Peptide Model Reaction fails to provide an adequate description of the full scope of the "flavors" encompassed by Applicants claims, including the claim limited to Arg-Phe, because the parameters of the reaction determine the scope of the "flavors," if any, the only flavor provided is chocolate, no compound/structure is set forth, and it is not routine to one of skill in the art to obtain a flavor/aroma/compound, as shown by Davies. There are no known structural characteristics in common between any of the flavor active compounds, only an aroma and even that according to Davies may or may not remain depending upon a plethora of factors that lack guidance.

Applicant appears to have created a specification based upon functional characteristics, the compounds making up a library that are obtainable through the Maillard reaction and produce a "flavor." The compounds appear to be described by what they do rather than what they are, i.e. flavor active compounds obtained by subjecting di-peptides to a reaction. It is also noted that not one of the peptides is shown to have a flavor from the reaction, there are only aromas associated with the sensory test.

For all of the reasons set forth above, Applicants arguments are not deemed persuasive and the rejection of claims 1, 5, 8-9, 17 and 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made final.

4. The rejection of claims 1, 5, 8-9, 17 and 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained and made final.

Applicants argue that the amendment of the claims to utilize the word "obtained" in place of "obtainable" provides the proper clarity regarding the breadth of the claims and that there is sufficient detail in the specification on the isolation and detection of the peptides from the natural pool (Specification, pp. 4-7), where 36 di-peptides where many of the different aroma profiles of reaction flavors were evaluated, including a set of 11 di-peptidesamples selected for large scale olfactory evaluation, showing a balanced chocolate aroma (Spec. pg.8, 2nd para.). Applicants further argue that the specification describes peptides that give rise to compounds with chocolate cocoa/caramel, cocoa, caramel, meat and bready flavors. Applicants again state that they detail a large selection of reducing sugars and solvents and disclose the detailed reaction condition under the peptide model reaction. Further, Applicants, argue that the sensory profiling is persuasive because six reaction samples were prepared, all of which were attributed a good chocolate aroma.

These arguments have already been addressed under the written description section and were not deemed persuasive there and are not deemed persuasive here for the same reasons. Changing the claim language to "obtained" fails to answer the argument that even if one or more of the di-peptide is subjected to the reaction, there is no structure that is ascertainable from the reaction, as it depends upon multiple factors and products within the reaction that are not set forth. As set forth above and explained in Davies, the plethora of reaction conditions, i.e. the sugar, the temperature, the pH, the time of each step and its relation to the other reactants, the

reactant, etc., can result in a plethora of compounds for one di-peptide (let alone more than one), which may not be flavor active.

Applicants' did not argue the state of the art but merely stated that the Maillard reaction is well-known and utilizing it is well known. However, Applicant's own Specification and Davies contradict this and they provide no evidence to the contrary. Applicants' own teachings of thermal reactions with hydrophobic amino acids under low water activity medium, while giving rise to chocolate-like aromas are complex in nature. Specification, pg. 2, lines 1-16. Moreover, as set forth above Davies discloses that the Maillard reaction, while well-known, is extremely complex and just beginning to become predictable with model system containing one sugar and amino acid, the chemistry of these compounds is not well-known, their formation mechanism remains obscure and can result in undesirable products. Davies, pp. 5-6, 9-10, and 30. Thus, the level of one of ordinary skill in the art would be high, as he would have to be able to take into account all of the factors of the Maillard reaction and balance them against one another and have the ability to differentiate the aroma/taste desired.

Applicants did not specifically argue the predictability of the art but merely made the assertion that the Maillard reaction is well known to persons having ordinary skill in the art and the operating conditions necessary for the Maillard reaction to occur are also well known to persons having ordinary skill in the art. However, as previously set forth and not disputed by any references the level of predictability in the art is very low as set forth above. There are no model systems above one sugar and one amino acid and the variables are numerous and interdependent. See Davies discussion above under written description, i.e. temperature, pH, time, etc.

The Specification fails to give adequate direction and guidance as to the means of utilizing a Maillard reaction to obtain a flavor active compound. While the Specification does set forth a Peptide Model Reaction, it is rife with omissions and has only one example of a sugar and reactant. These omissions and the problems with only one sugar and reactant are discussed above under written description and result in the claimed invention being devoid of structural and or functional constraints regarding the compounds encompassed by the claimed "flavor active compounds."

Applicants arguments that they have produced a variety of aromas as working examples is clearly not commensurate in scope because although they tested 44 di-peptides (22 of which are claimed) under the "Maillard reaction", they did not test any multiple combinations nor did they test multiple parameters, thus the working examples directed to the Peptide Model Reaction and Sensory Profiling from that Model Reaction are clearly not commensurate in scope to the claimed invention, which is drawn to all flavor active compounds obtained by subjecting one or more peptides selected from the group consisting of 24 di-peptides to a Maillard reaction with reducing sugars under condition sufficient to form the flavor active compound, when only one sugar is set forth, only one reactant, no parameters on time for preheating/mixing with the reactant, an up to limitation on the second heating, no guidance on the amount of water, no other reactants, the only one pH range, all of which are discussed above and give different flavor active compounds under the written description rejection. Moreover, while it appears that 44 di-peptides were subjected to some sort of an aroma profile, it also appears that only 6 were actually tested for aroma because it states that a maximum of 6 reaction samples was evaluated by sniffing at any given time. No real data is supplied other than for the six that were attributed a

good chocolate aroma. Moreover, the aroma is only to chocolate not to all of the different possible aromas/flavors, i.e. the different fruits, vegetables, flowers, meats, bread, etc. Nor were they directed to the vast variety of chocolate aromas, i.e. bittersweet, vanilla, dark, coffee, etc and as this is a **flavor** active compound **no examples** of **taste** were provided. As previously set forth flavor and aroma are different.

Thus, the Specification provides insufficient disclosure to support or enable a flavor active compound obtained by subjecting one or more of the 24 di-peptides or even just the one di-peptide Arg-Phe or a process for preparing a flavor, which comprises subjecting one or more of the 24 or even just the one di-peptide Arg-Phe to a Maillard reaction with reducing sugars under conditions sufficient to form the flavor for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. The rejection of claims 1, 5, 8-9, 17 and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained and made final.

Applicants arguments that the amendments to independent claims 1 and 17 address the issues is not persuasive. The term subjected remains and the rationale for the other rejections is set forth below and is also addressed in the written description/enablement rejections.

The term flavor renders the claim indefinite because it is unclear whether it is meant to be a taste, an aroma, a combination of both, or situational, i.e. either/or. Applicants' arguments that the words are all interchangeable is not persuasive for the reasons set forth above. Flavor has a plain meaning that clearly includes taste and is not exclusive to aroma. Where applicant acts as

his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Applicant failed to provide any definition for the term flavor in the specification or any dictionary definitions that would support their position that these terms are interchangeable in ordinary and customary usage and thus, the ordinary meaning must apply.

The phrase "flavor active compound" render the claim indefinite because it is unclear what a flavor active compound is, the structure is unknown, what constitutes a flavor active compound is unknown – is it a compound that has an aroma or a taste or both or sometimes one or the other or both, the Specification varies on its usage. The examiner was unable to locate the phrase "flavor active compound" in any dictionary. Flavor itself has a plain meaning that clearly includes taste and is not exclusive to aroma. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Applicant failed to provide any definition for the term flavor in the specification or any dictionary definitions that would support their position that these terms are interchangeable in ordinary and customary usage and thus, the ordinary meaning must apply.

The term subjecting renders the claim indefinite because it is unclear what Applicant intends to encompass/mean by subjecting, as it is not an art recognized term in relation to a reaction. It is suggested that Applicants amend the claim to recite, "reacting".

The phrase "with/to a Maillard reaction with reducing sugars" renders the claim indefinite because it is unclear when the sugars participate in the reaction, i.e. are they reacted with the peptides or at a later phase. It is suggested that the claim be amended to state that "and a reducing sugar to a Maillard reaction".

The phrase "under conditions sufficient to form the flavor active compound" is vague and indefinite" because the reaction itself is unpredictable it is unknown what conditions would be sufficient (see arguments above), also it lack metes and bounds because it is unclear what conditions are necessary in order to carry out the claimed process. This has been addressed under the written description and enablement rejections as set forth by Davies, et al. who demonstrates that this is not a reaction readily understood by one of ordinary skill in the art and no contradictory art has been provided by Applicant to show that it is readily understood by one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 1, 5, and 17 under 35 U.S.C. 102(b) as being anticipated by Otagiri, et al., Studies on a Model of Bitter Peptide Including Arginine, Proline, and

Phenylalanine Residue. I. Bitter Taste of Di- and Tripeptides and Bitterness Increase of the Model Peptides by Extension of the Peptide Chain, Agric. Biol. Chem., 1985, Vol. 49, Iss. 4, pp. 1019-1026 is maintained and made final.

Otagiri discloses a flavor active compound obtained from Arg-Phe. Applicant argues that the claim language states that the flavor active compound is obtained by the subjecting the di-peptide to a Maillard reaction and thus the rejection should fall. However, the Applicant does not state that the compound is not a flavor active compound nor that it is not the same compound structure or that the Maillard reaction would impart any special structural features or that this product would not be a resulting product of the Maillard reaction. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) The reference discloses that Arg-Phe was synthesized and became a bitter tasting compound. See pages 1019, 1021-1022 and 1025 specifically. Applicant has not shown rationale why this is not one of the same products of the Maillard reaction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The rejection of claims 1, 5, 8-9, 17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Otagiri, et al., Studies on a Model of Bitter Peptide Including Arginine, Proline, and Phenylalanine Residue. I. Bitter Taste of Di- and Tripeptides and Bitterness Increase of the Model Peptides by Extension of the Peptide Chain, Agric. Biol. Chem., 1985, Vol. 49, Iss. 4, pp. 1019-1026 in view of Girsh (US 5,753,296) is maintained and made final.

Applicants argue the motivation to combine in Otagiri and Girsh stating that there are just four types of taste sensations and the present invention relates to chocolate and that since Girsch is sweetening cocoa powder that may be made sweeter by a Maillard reaction of the cocoa powder protein and the lactose of the diary permeate that one of ordinary skill would not have been motivated to use it with Arg-Phe to obtain the body and taste of chocolate. However, the examiner was not using Girsh as a motivation to obtain the taste of chocolate, but as a motivation to soften the bitter taste of Arg-Phe. Applicants clearly admit that cocoa is full of bitter peptides, whether large or small and That Girsh teaches that utilizing lactose sweetens/soften their taste. Thus, the motivation remains to combine the references as the motivation and outcome does not have to be the same as applicants. Thus, as per 1, 5, 8, and 9, Otagiri discloses the di-petide, Arg-Phe, and discloses that it has a bitter taste. See pages 1019, 1021-1022 and 1025 specifically. However, Otagiri does not disclose that the flavor active compound is obtained by subjecting Arg-Phe to the Maillard reaction with reducing sugars. Girsh discloses that is desirable to react cocoa powder protein (bitter protein) with lactose, i.e. a reducing sugar in the Maillard reaction in order to soften/sweeten the taste. Col. 11, lines 32-41. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the Maillard reaction

with the bitter di-peptide of Otagiri and a reducing sugar to soften the bitter compound, i.e. making it more palatable.

As per Oh, Applicants argue that fructose is only used with Gly based di-peptides and that Arg-Phe is nothing like the Glycine di-peptidesHowever, this misses the point of the reference. Page 44 is a generic teaching of N-terminal peptides that form DKPs, i.e. pyrazines, from fructoses as taught in Rizzi, 1989. One of ordinary skill in the art would expect that any peptide would undergo this reaction to form a DKP and the by-product. It does not have to produce the same flavor that Applicant produces. It merely has to have some expectation that it would produce a flavor and as it is starting out as a bitter flavor, there is no reason to suspect that it would not have some flavor. Applicants have not stated otherwise. Thus, Applicants arguments that Oh is a teaching away is not persuasive, as Oh is really a general teaching.

As per claims 17 and 20, Otagiri and Girsh disclose as set forth above. Neither Otagiri nor Girsh disclose that the reducing sugar is fructose. However, fructose is the sugar that naturally occurs in fruits and would routinely or inherently be present in the confectionary/flavoring components, as conventional. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized fructose in the place of lactose in the Maillard reaction as taught in Girsch with the peptide of Otagari.

Thus, the rejection of claims 1, 5, 8-9, 17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Otagiri, et al., Studies on a Model of Bitter Peptide Including Arginine, Proline, and Phenylalanine Residue. I. Bitter Taste of Di- and Tripeptides and Bitterness Increase of the Model Peptides by Extension of the Peptide Chain, Agric. Biol. Chem., 1985, Vol. 49, Iss. 4, pp. 1019-1026 in view of Yu-Chiang Oh, Flavor Chemistry of the Maillard

Reaction of Dipeptides, Rutgers The State University of New Jersey – New Brunswick, 1992, pp. 1-154.

As per 1, 5, 8-9, 17 and 20, Otagiri discloses that the di-petide, Arg-Phe, has a bitter taste. See pages 1019, 1021-1022 and 1025 specifically. However, Otagiri does not disclose that the flavor active compound is obtained by subjecting Arg-Phe to the Maillard reaction with reducing sugars, specifically fructose. Oh discloses that the contribution of dipeptides in the generation of balance food aroma can not be neglected, that it is known that many foods contained a variety of peptides, which play an important role in the contribution to the intrinsic property of a particular food aroma and that when Mohr, et al. conducted an experiment by pyrolyzing a mixture of peptides plus amino acids with fructoses, they found the aroma produced was much closer to that of roasted cocoa beans than when peptides or amino acids alone were pyrolyzed with fructose. See, pg. 40. Additionally, Oh discloses that dipeptides/tripeptides are produced by thermal degredation during roasting, particularly dikeopiperazines (DKPs), which are known to give a bitter flavor in cocoa bean and sake. See, pp. 43 and 45. Oh further discloses that Rizzi observed that certain peptides, when reacted with fructose produced relatively more pyrazines than respective amino acid mixtures, i.e. the Maillard reaction of fructose with the peptides apparently facilitated peptide hydrolysis and formation of Strecker aldehydes. See, pg. 45. Thus, it would have been obvious to one of ordinary skill in the art to subject the di-peptide, Arg-Phe, of Otagiri, to/in the Maillard reaction with the reducing sugar fructose to obtain more pyrazines, i.e. aroma/flavor compounds.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

June 8, 2005

MICHAEL MELLER
PRIMARY EXAMINER